

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### The Effect of Nose and Mouth Disinfection with Chlorhexidine on indicators of respiratory infections in intubated patients with mechanical ventilation

#### Protocol summary

##### Summary

The purpose of this study is to determinate the effect of disinfection of "mouth and nose" compared with antiseptic "mouth alone" with chlorhexidine solution on indicators of respiratory infection in intubated patients under mechanical ventilation. Research design: A randomized, double-blind clinical trial. Inclusion Criteria: The patient has oral endotracheal tube and connected to ventilator; The patient does not have nasogastric tube; On arrival to the ICU respiratory infection symptoms was not seen. Exclusion criteria: The patient is less than 48 hours under mechanical ventilation; Symptoms of respiratory infection is observed in the first two days of mechanical ventilation. Sample size: 70 intubated patients under mechanical ventilation. Interventions: In the intervention group, antiseptic mouth and nose wash was done every 8 hours with 10 ml of 0.2% chlorhexidine preparation solution by the applicator for 30 seconds. in the control group, only oral antiseptic was used. Intervention time: For all patients, first intervention is performed in the first 12 hours connected to ventilator and this work continues until the end of the fifth day of mechanical ventilation. Primary outcomes: study of respiratory infection indicators based on clinical pulmonary infection score, including: amount of body temperature, amount and kind of Tracheal secretions, amount of Blood leukocytes, ratio of arterial Oxygenation, changes of chest radiographic and culture of tracheal secretions. Secondary outcomes: amount of Ventilator associated Pneumonia

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016051927969N1**  
Registration date: **2016-07-09, 1395/04/19**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2016-07-09, 1395/04/19

##### Registrant information

###### Name

Mahdi Alimi

###### Name of organization / entity

Mashhad University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 51 3841 2081

###### Email address

alimim1@mums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice chancellor for Mashhad University of Medical Sciences

##### Expected recruitment start date

2016-06-21, 1395/04/01

##### Expected recruitment end date

2016-07-22, 1395/05/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The Effect of Nose and Mouth Disinfection with Chlorhexidine on indicators of respiratory infections in

intubated patients with mechanical ventilation

## Public title

The Effect of Nose Disinfection with Chlorhexidine on Respiratory Infection

## Purpose

Prevention

## Inclusion/Exclusion criteria

Inclusion Criteria: The satisfaction of patient's attendant to participate in the study; The patient's age is more than 18 years; The patient has endotracheal tube through the mouth; The patient has not nasogastric tube; Expecting mechanical ventilation for at least 48 hours; On arrival to the ICU lung infiltration on chest radiograph Does not exist; At least two of the three clinical criteria indicators of ventilator associated pneumonia (rectal temperature less than 35 or more than 38 degrees Celsius, leukocyte count of less than 4,000 or more than 12,000 per cubic millimeter of blood and purulent tracheal secretions) does not exist. Exclusion criteria: desire to continue participation in the study; Allergic reaction to chlorhexidine; Clear aspiration; At least two of the three clinical criteria indicators of ventilator associated pneumonia exist in the first or second day of mechanical ventilation

## Age

From 18 years old

## Gender

Both

## Phase

N/A

## Groups that have been masked

No information

## Sample size

Target sample size: 70

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Double blinded

## Blinding description

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

The ethics committee of Mashhad University of Medical Sciences

##### Street address

Qoreishi Building, Daneshgah St, Mashhad

##### City

Mashhad

##### Postal code

9177899191

##### Approval date

2015-11-07, 1394/08/16

##### Ethics committee reference number

IR.MUMS.REC.1394.493

## Health conditions studied

### 1

#### Description of health condition studied

Pneumonia

#### ICD-10 code

J18.9

#### ICD-10 code description

Pneumonia, unspecified

## Primary outcomes

### 1

#### Description

Amount of Body Temperature

#### Timepoint

up to Five Days after beginning of Intervention

#### Method of measurement

By Glass Thermometer for Axillary in Degrees Celsius

### 2

#### Description

Amount of Tracheal secretions

#### Timepoint

up to Five Days after beginning of Intervention

#### Method of measurement

Based on The Required Frequency of Tracheal Suctioning

### 3

#### Description

Kind of Tracheal secretions

#### Timepoint

up to Five Days after beginning of Intervention

#### Method of measurement

On the basis of color, odor and secretions concentration and according to the nurse caring for the patient

### 4

#### Description

Amount of Blood leukocytes

#### Timepoint

up to Five Days after beginning of Intervention

#### Method of measurement

By blood test

### 5

#### Description

Ratio of Arterial Oxygenation

## **Timepoint**

up to Five Days after beginning of Intervention

## **Method of measurement**

By Analyze of Arterial Blood Gases

## **6**

### **Description**

changes of Chest radiographic

### **Timepoint**

up to Five Days after beginning of Intervention

### **Method of measurement**

By the removable radiological devices (portable)

## **7**

### **Description**

Culture of tracheal secretions

### **Timepoint**

up to Five Days after beginning of Intervention

### **Method of measurement**

Quantitative culture with Gram stain

## **Secondary outcomes**

## **1**

### **Description**

Ventilator associated Pneumonia

### **Timepoint**

Up to five days after beginning of intervention

### **Method of measurement**

By Clinical Pulmonary Infection Score

## **2**

### **Description**

The relationship between clinical criteria and diagnosis of pneumonia

### **Timepoint**

Up to five days after beginning of intervention

### **Method of measurement**

By Clinical Pulmonary Infection Score

## **Intervention groups**

## **1**

### **Description**

In the intervention group, mouthwash (disinfection cheeks, gums, palate, tongue and teeth) every 8 hours with 10 ml of ready solution of 0.2% chlorhexidine is performed by the applicator for 30 second. Also every 8 hours after oral antiseptic, anti-infectious of nasal anterior openings is performed with 0.2% chlorhexidine solution by cotton swab. This continues until the end of the fifth day of mechanical ventilation.

### **Category**

Prevention

## **2**

### **Description**

In the control group, mouthwash (disinfection cheeks, gums, palate, tongue and teeth) every 8 hours with 10 ml of ready solution of 0.2% chlorhexidine is performed by the applicator for 30 second. This continues until the end of the fifth day of mechanical ventilation. In this group is not done disinfection of nose.

### **Category**

Prevention

## **Recruitment centers**

## **1**

### **Recruitment center**

#### **Name of recruitment center**

Shahid Kamyab Hospital

#### **Full name of responsible person**

#### **Street address**

Shahid Kamyab Hospital, Fadaieyan Eslam Avenue, Nakhrisi Square, Mashhad

#### **City**

Mashhad

## **Sponsors / Funding sources**

## **1**

### **Sponsor**

#### **Name of organization / entity**

Vice chancellor for research, Mashhad University of Medical Sciences

#### **Full name of responsible person**

Dr. Saeid Eslami

#### **Street address**

Ghoraishy Building, University St, Mashhad

#### **City**

Mashhad

### **Grant name**

### **Grant code / Reference number**

### **Is the source of funding the same sponsor organization/entity?**

Yes

### **Title of funding source**

Vice chancellor for research, Mashhad University of Medical Sciences

### **Proportion provided by this source**

100

### **Public or private sector**

*empty*

### **Domestic or foreign origin**

*empty*

### **Category of foreign source of funding**

*empty*

### **Country of origin**

### **Type of organization providing the funding**

*empty*

## Person responsible for general inquiries

### Contact

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Mahdi Alimi

**Position**

Nursing Expert, Nurse

**Other areas of specialty/work****Street address**

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## Person responsible for updating data

### Contact

**Name of organization / entity****Full name of responsible person**

Mhdi Alimi

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Zahra Sadat Manzari

**Position**

Nursing Ph.D, Assistant Professor

**Other areas of specialty/work****Street address**

Faculty of Nursing and Midwifery, Ibn-e Sina St,  
Chaharah Doktora Crossing, Mashhad

**City**

Mashhad

**Postal code****Phone**

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*